

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:
All Actions

No. 1:19-md-2875-RBK

Hon. Robert B. Kugler
Hon. Karen M. Williams
Hon. Thomas I. Vanaskie

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
ZHP'S MOTION TO SEAL**

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INTRODUCTION

The Court is familiar with and has preserved the public's right to access court records already in this litigation. Ignoring this, and fearing public knowledge regarding its extensive cGMP failures in the manufacture of pharmaceuticals that led to a worldwide recall of blood pressure drugs, ZHP mischaracterizes the content of [ECF 1298](#)'s Exhibit KK, which is a ten-page deposition excerpt in which its employee Xiaodi Guo mostly refused to answer substantive questions about an email he and Baohua Chen received regarding those failures. For the Court's convenience, Plaintiffs will email Exhibit KK and [ECF 1298](#), together with a courtesy copy of this filing.

Overlooked by ZHP, the Court has already denied motions to seal documents containing similar and far more damning information, including numerous FDA inspection reports. These inspection reports established that ZHP violated numerous cGMPs when it manufactured valsartan contaminated with carcinogenic nitrosamines. The public has a right to understand the full extent to which these cGMP violations predate the recall of ZHP's valsartan, and the extent to which ZHP ignored its own internal knowledge of these violations. Importantly, ZHP's embarrassment at the Exhibit's contents is of no import on this motion, and the Court has already rejected ZHP's speculative arguments that competitors could use such embarrassment to their financial advantage. ZHP's attempt to invoke a "self-evaluative privilege" is undermined by its reliance on a long-overturned New Jersey Superior Court case. The Court should therefore deny ZHP's motion to seal.

LEGAL ARGUMENT

I.

THE COURT SHOULD DENY ZHP’S MOTION TO SEAL DOCUMENTS THAT DO NOT MERIT CONFIDENTIALITY AND CONTAIN HEALTH AND SAFETY INFORMATION

“[I]n cases involving large-scale discovery, the court may construct a broad umbrella protective order upon a threshold showing by the movant of good cause.” *In re Avandia Mktg., Sales, and Prods. Liab. Litig.*, 924 F.3d 662, 671 n.5 (3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 n.17 (3d Cir. 1994)). “However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes.” *In re: Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Products Liability Litigation*, 512 F. Supp. 3d 546, 550 (D.N.J. 2021). This Court has previously noted that **“the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery.”** *Id.* (emphasis added).

Thus, when a party challenges a designation under an umbrella protective order, “the party seeking to maintain the seal must justify the continued sealing of those documents.” *Avandia*, 23 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17). “In *Pansy v. Stroudsburg*, 23 F. 3d 772 (3rd Cir. 1994), the court expounded on the burden to justify confidentiality.” *Valsartan*, 512 F. Supp. 3d at 550. There, the Third Circuit set forth seven factors to consider when deciding a motion to seal:

1. whether disclosure will violate any privacy interests;
2. whether the information is being sought for a legitimate purpose or for an improper purpose;

3. whether disclosure of the information will cause a party embarrassment;
4. **whether confidentiality is being sought over information important to public health and safety;**
5. whether the sharing of information among litigants will promote fairness and efficiency;
6. whether a party benefitting from the order of confidentiality is a public entity or official; and
7. **whether the case involves issues important to the public.**

Avandia, 924 F.3d at 671 (emphasis added) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy*, 23 F.3d at 787-91)); *see also* [ECF 1269](#), p. 6-7. In *Pansy*, the Third Circuit also held that “**where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality** whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law.” 23 F.3d at 791; *see also* [ECF 1269](#), p. 7. Importantly, this standard, which ZHP cannot meet – just as Torrent could not meet it – applies “when [a court] review[s] orders preserving the confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26.” *Avandia*, 924 F.3d at 670 (citing *Pansy*, 26 F.3d at 783-92); *see also* [ECF 1269](#), p. 7. All of these factors cut against ZHP, which has the heavy burden on this motion.

“**[T]he more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access.**” *Avandia*, 924 F.3d at 670 (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)); *see also* [ECF 1269](#), p. 7.

The common law right of access “antedates the Constitution.” *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d

[339,] 343 [(3d Cir. 1986)]. The right of access “promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court.” *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access “diminishes possibilities for injustice, incompetence, perjury, and fraud.” *Id.* Moreover, “the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness.” *Id.*

Avandia, 924 F.3d at 672. Thus, **once a document “has been filed with the court ... or otherwise somehow incorporated or integrated into a district court’s adjudicatory proceedings,” “a presumption of access attaches.”** *Id.* (emphasis added) (quoting *In re Cendant Corp.*, 260 F.3d at 192); *see also* [ECF 1269](#), p. 8.

“To overcome that strong presumption, the District Court must articulate ‘the compelling, countervailing interests to be protected,’ make ‘specific findings on the record concerning the effects of disclosure,’ and ‘provide[] an opportunity for interested third parties to be heard.’” *Avandia*, 924 F.3d at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194); *see also* [ECF 1269](#), p. 8. “In delineating the injury to be prevented, specificity is essential,” so **“[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.”** *Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (emphasis added); *see also* [ECF 1269](#), p. 8. In sum, **“[c]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants.”** *Avandia*, 924 F.3d at 673 (emphasis added) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)); *see also* [ECF 1269](#), p. 8. ZHP’s motion is built entirely on broad allegations of harm, nothing more.

Moreover, although some of the seven *Pansy* factors are relevant to a court’s analysis under the common law standard, two are explicitly not considered. *Avandia*, 924 F.3d at 677. First, the Third Circuit has “repeatedly said that **concern about a company’s public image,**

embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access.” *Id.* (emphasis added) (collecting cases). Second, “a person’s motive for inspecting or copying judicial records is irrelevant under the common law right of access.” *Id.* at 677.

In considering the remaining five factors, the Third Circuit has put its “thumb on the scale in favor of openness—the strong presumption of public access[:]”

[T]he public’s right of access must be the starting point, not just one of multiple factors. The scale is tipped at the outset in favor of access. And the right of access is not a mere formality—it “promotes public confidence in the judicial system”; “diminishes possibilities for injustice, incompetence, perjury, and fraud”; and “provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness.” *Littlejohn*, 851 F.2d at 678. **These interests are particularly important in a case such as this one, which implicates the public’s trust in a well-known and (formerly) widely-used drug.**

Avandia, 924 F. 3d at 677 (emphasis added). Moreover, “[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm.” *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196). That showing cannot be made by ZHP since the extensive cGMP failures are a matter of public record, and the failed manufacturing processes at issue are banned. Moreover, “blanket assertions of harm that ‘could’ come to fruition fall short of the clearly defined and serious injury that [a movant] must articulate to obtain sealing under any standard.” *Id.* at 679. As discussed below, ZHP fails that test, and cannot meet it with regard to presumptively public documentation of the facts surrounding its wholesale contamination of a trusted blood pressure drug, a drug that is no longer sold by ZHP in the United States.

After the Third Circuit vacated and remanded its original decision to seal the documents in *Avandia*, the trial court applied the correct standard and wrote:

Justice Brandeis famously declared that “sunlight is the most powerful of all disinfectants.” Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.

In re Avandia Mktg, Sales Practices and Prods. Liab. Litig., 484 F. Supp. 3d 249, 268 (E.D. Pa. 2020) (emphasis added) (footnote and citations omitted).

In one of its prior confidentiality rulings in this case, the Court noted that it “is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents.” *Valsartan*, 2512 F. Supp. 3d at 553. Instead, the Court found that “[a]t bottom, Torrent's emails involve what appears to be routine business communications.” *Id.* at 554. The Court also rejected the argument that the authors or recipients expected the documents to remain confidential, explaining “[o]therwise, large swatches of routine emails would be kept under wraps.” *Id.*

In this motion, ZHP has asked the Court to seal Exhibit KK of [ECF 1298](#) as well as the brief's short paragraph discussing that exhibit. In accordance with Third Circuit precedent, ZHP's proposed order concedes that the common law public right of access applies to this material. ([ECF 1468-3](#), p. 6). *See also Avandia*, 924 F.3d at 672.

In addition to “the strong presumption” against sealing these judicial records, and the fact that there is nothing sensitive about the documents on their face, this Court should recognize the significant public interest in understanding the nitrosamine contamination at issue in this case. *Avandia*, 924 F. 3d 677. ZHP was the first pharmaceutical manufacturer to recall its drugs due to their contamination with carcinogenic nitrosamines, and the issue is not limited to valsartan,

losartan, and irbesartan. FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, <https://tinyurl.com/1k9w9jid>; FDA, *Information about Nitrosamine Impurities in Medications*, <https://tinyurl.com/1tu3nih0>. **There is an ongoing public investigation into the cause of this widespread contamination, whether it has occurred with other drugs, and how to prevent it in the future, on top of the FDA's firm determination that the contamination was wrongful and unacceptable, resulting in a complete recall and import ban against ZHP.** In fact, ZHP is still banned from importing its valsartan into the United States because it has not addressed its contamination to the satisfaction of the FDA. FDA, Import Alert 66-40, <https://tinyurl.com/3jxjmexc>.

There is simply no reasonable argument for shielding documentation of these dangerous safety failures from the public. **ZHP cannot hide the information needed for a true understanding of the nitrosamine contamination of its valsartan.** As explained in further below, this Court should therefore deny ZHP's motion to seal.

1. 5/20/2021 Xiaodi Guo Dep. Tr. 131-140 ([ECF 1298](#), Ex. KK): This is a ten-page deposition excerpt where Xiaodi Guo repeatedly states that he is unable to answer questions related to an email that he and Baohua Chen received. ZHP claims that "this exhibit [should] be sealed because it describes in detail internal ZHP emails" "describe[ing] the results of an internal audit of ZHP's finished dose manufacturing facility conducted by the Vice President of Quality Assurance for Princeton in January 2021, as well as steps taken by the ZHP parties in response." ([ECF 1468-6](#), p. 2). **A review of the actual deposition testimony shows that Plaintiffs asked about the audit in very general terms and Xiaodi Guo was unable to answer any substantive**

questions concerning the audit.¹ Moreover, the public already has access to numerous FDA inspection reports detailing ZHP’s failure to comply with current good manufacturing processes (cGMPs), many of which resulted in the contamination of its valsartan with carcinogenic nitrosamines. *See Valsartan*, 512 F. Supp. 3d at 556 (holding, “To the extent similar documents are designated Confidential, the designations shall be removed”). The public has a strong interest in understanding the extent to which these cGMP violations significantly predate the recall and were understood within ZHP itself. *Avandia*, 924 F. 3d at 677 (holding, “**These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.**”) (emphasis added).

The Court has already rejected ZHP’s “speculative” argument that the disclosure of audits “would harm it competitively by causing confusion among its customers that could be exploited by ZHP’s competitors.”² ([ECF 1269](#), p. 10 n.8). In an effort to have the Court reverse this prior ruling, ZHP cites completely inapposite cases that sealed detailed proprietary trade secrets. ([ECF 1468-3](#), p. 8-9). To be clear, Exhibit KK does not include any such information, and even if it did that would be overcome by the fact that this information is at the center of a worldwide public health crisis.

¹ **Despite Local Civil Rule 5.3(c)’s requirement that “[a]ny motion and supporting papers to seal or otherwise restrict public access shall be available for review by the public,” ZHP attached a Declaration of Jun Du to its motion that is unnecessarily far more detailed than Exhibit KK itself.** The Court should order ZHP to put this declaration on the docket immediately.

² The Court only granted ZHP’s motion to seal ZHP00305868 because “making this document publicly accessible ‘would violate ZHP’s confidentiality agreement with [the supplier], which prohibits the disclosure of confidential information absent reasonable advance notice and compelling applicable law.’” (ECF 1269, p. 10). As already explained, Exhibit KK is a deposition transcript asking a non-responsive witness about an email regarding an internal audit. The Court will not cause ZHP to breach any confidentiality agreement by denying its motion to seal this exhibit.

ZHP also claims that allowing for the disclosure of the transcript would “result in participants being less forthcoming, or auditors being less direct in their conclusions for fear of embarrassment or misunderstanding, depriving [it] of the ability to conduct candid audits of their manufacturing facilities.” ([ECF 1468-6](#), p. 2). First, any potential embarrassment to ZHP is irrelevant to the Court’s decision of this motion. *See Avandia*, 924 F.3d at 677; *Valsartan*, 512 F. Supp. 3d at 550. Second, ZHP also states that these audits are intended to find problems ahead of FDA inspections and to otherwise ensure compliance with its legal obligations as sellers of pharmaceuticals in the United States. *Id.* These strong and legally enforceable incentives will remain even if these types of audits become public when filed on the docket of a multidistrict litigation concerning the defendants’ failure to comply with cGMPs, as required by *Avandia*, 924 F. 3d at 677. Afterall, “**sunlight is the most powerful of all disinfectants.**” *Avandia*, 484 F. Supp. 3d at 268.

Attempting to circumvent this Third Circuit precedent, ZHP cites and grossly misapplies a factually inapplicable case, *Neorx Corp. v. Immunomedics Inc.*, No. 92-2853, 1993 WL 493880, at *2-3 (D.N.J. Sep. 30, 1993), in support of a “self-evaluative privilege.” ([ECF 1468-3](#), p. 9-10). However, that nearly thirty-year-old unpublished case is out of step with the controlling precedents in the Third Circuit and relied on a broken foundation—a now reversed New Jersey Superior Court case—*Wylie v. Mills*, 195 N.J. Super. 332, 339 (1984)). In reversing *Wylie*, the New Jersey Supreme Court held:

[W]e are not as confident as the court in *Wylie* that absolute confidentiality is always essential to encourage frank, productive self-evaluation. It is not so clear that disclosure inevitably will discourage candid self-criticism. As the court noted in *Tharp, supra*, in the employment context:

Permitting disclosure of an employer's self-critical analyses of its equal employment efforts may actually cause [an employer] to

engage in a more honest assessment of its efforts because flaws in those analyses may be brought to light in civil litigation. The sunshine of public scrutiny would thus act as a catalyst to promote, not inhibit, employers to engage in full and candid equal employment assessments.... [A] weakly worded, unimaginative, and unaggressive analysis ... may be more damning than a candid evaluation recognizing a company's weaknesses and expressing a serious commitment to overcome those weaknesses.

Payton v. N.J. Turnpike Authority, 148 N.J. 524, 545-47 (1997) (quoting *Tharp v. Sivyer Steel Corp.*, 149 F.R.D. 177, 183 n.13, 184 n.16 (S.D. Iowa 1993). (citation omitted)) (emphasis added).

This explicit reversal is perhaps why Westlaw does not show a single citation to *Neorx Corp. v. Immunomedics Inc.* The New Jersey Supreme Court's approach to self-critical analysis comports with the Third Circuit's policy that "**sunlight is the most powerful of all disinfectants.**" *Avandia*, 484 F. Supp. 3d at 268.

2. First Full Paragraph of Page 22 of Plaintiffs' Opposition to ZHP's Motion for a Protective Order Precluding the Deposition of Baohua Chen (ECF 1298): This paragraph describes Exhibit KK in very general terms. Plaintiffs only redacted it out of an abundance of caution. There is no basis to seal this information for the same reasons set forth above regarding Exhibit KK.

CONCLUSION

For the foregoing reasons, the Court should deny ZHP's motion to seal. In accordance with Local Civil Rule 5.3, Plaintiffs have attached a proposed order as Exhibit A of this brief.

Dated: August 23, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2021, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Adam M. Slater

Adam M. Slater